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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,876	07/20/2001	John Howard Skerritt	Q-64066	5306

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Sghrue Mion Zinn
Macpeak & Seas
2100 Pennsylvania Avenue NW
Washington, DC 20037-3202

EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/830,876	Applicant(s) SKERRITT, JOHN HOWARD	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-14 and 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment

1. Applicant's amendment filed on 30 August 2004 has been received. Claims 2 and 15-22 have been cancelled. Claims 23-30 have been added. Claims 1, 3-14 and 23-30 are pending.
2. All rejections not reiterated herein below are withdrawn in view of the amendment and/or cancellation of the claims.

Claim Rejections - 35 USC § 112, Second Paragraph

3. Claims 14, 24, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 29 are confusing because it is unclear how a *quantity* of alpha-amylase in a test sample can be measured by comparing the detected binding of the test sample to alpha-amylase *enzyme activities* in a standard, or how it can be measured by comparing to Falling Numbers. Because enzyme activities and Fall Numbers are obtained using completely different methods of measuring, it is unclear how one can correlate results obtained from these different methods. For example, the activity of an enzyme is not necessarily related to its concentration, therefore, it is unclear how the correlation is made as claimed. The same is true for Falling numbers, i.e. Falling Numbers are usually expressed in term of viscosity of a sample and is normally a means to gauge the level of preharvest sprout activity in cereal grains such as wheat and barley.

Claim 24 is confusing because it is unclear how the aqueous extract comprises NaCl or CaCl₂. In other words, the claim appears to recite that the test sample, itself, comprises

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comprises NaCl or CaCl₂, and not the aqueous extraction solution as disclosed by the specification.

Claim Rejections - 35 USC § 112, First Paragraph

4. Claims 25-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Claims 25-29 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for determining the presence or amount of alpha-amylase in a sample, does not reasonably provide enablement for a method for determining weather damage in a plant or crop. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 25 recites a method for determining weather damage in a plant or crop by detecting the presence of alpha-amylase in a sample of the plant or crop. Such a method does not have support in the specification as originally filed. The specification discloses a method for measuring alpha-amylase in a test sample and briefly mentions that alpha amylase is related to preharvest sprouting which could be due to weather damage. However, the specification fails to positively correlate the presence of alpha-amylase to weather damage. Preharvest sprouting could be caused by contamination or storage condition of grain silos that does not involve weather damage, per se.

Furthermore, the specification does not enable a method for determining weather damage in a plant or crop as claimed because no data is presented nor correlations made in the specification as to the amount of alpha-amylase detected and weather damage.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3-14, 23 and 25-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sander et al., (Journal of Immunological Methods. 210 (1997) 93-101).

Sanders discloses a two-site enzyme-linked immunosorbent assay for alpha-amylase using monoclonal antibodies that binds to distinct epitopes of the alpha-amylase. Sanders teaches using extracts of wheat flour, rye flour and baker's yeast alpha-amylase and comparing the results with a standard curve solution. See page 95-97.

Even though Sanders is silent with respect to the epitopes of alpha-amylase to which the antibodies binds are those disclosed as SEQ ID NO. 1, 2 and 3, Sanders does disclose all of the limitation of claim 1 including binding of the antibodies to distinct epitopes of alpha-amylase and since SEQ ID NO. 1, 2 and 3 are deemed to be inherently possessed by the alpha-amylase of the prior art, the claims are anticipated by or, in the alternative, obvious over the teachings of Sanders. See *In re Best, Bolton, and Shaw* (CCPA) 195 USPQ 430.

9. Claims 1, 3-14 and 23-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over LeCommandeur et al., (Hybridoma. Vol. 9, No. 2, 1990, pp. 177-187).

LeCommandeur discloses a sandwich ELISA for barley alpha-amylase using monoclonal antibodies that binds to different epitopes of the alpha-amylase. See page 178, *Materials and Methods*. LeCommandeur teaches the use of an extraction solution comprising malate buffer, CaCl_2 and NaCl at pH 5.2 to prepare an extract from 6-days germinated grains of barley.

Even though LeCommandeur is silent with respect to the epitopes of alpha-amylase to which the antibodies binds are those disclosed as SEQ ID NO. 1, 2 and 3, LeCommandeur does disclose all of the limitation of claim 1 including binding of the antibodies to distinct epitopes of alpha-amylase and since SEQ ID NO. 1, 2 and 3 are deemed to be inherently possessed by the alpha-amylase of the prior art, the claims are anticipated by or, in the alternative, obvious over the teachings of Sanders. See *In re Best, Bolton, and Shaw* (CCPA) 195 USPQ 430.

Response to Arguments


10. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
11/3/04